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10/28/2003

Joseph A. Gonzales

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APPLIED MEDICAL RESOURCES CORPORATION

22872 Avenida Empresa

Rancho Santa Margarita, CA 92688

EXAMINER

VU, QUYNH-NHU HOANG

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/695,295  
Filing Date: October 28, 2003  
Appellant(s): GONZALES ET AL.

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Joseph Gonzales  
Boun Pravong  
Richard Ewers  
Richard Myers  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 11/12/09 appealing from the Final Office action mailed 05/15/09.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

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**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

4,143,853	Abramson	3-1979
4,946,133	Johnson et al.	8-1990
5,460,616	Weinstein et al.	10-1995
2003/0139756	Brustad	7-2003

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1-2, 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abramson (US 4,143,853) in view of Weinstein (US 5,460,616) or Brustad (US 2003/0139756) and Johnson et al. (US 4,946,133).**

Abramson discloses a surgical valve comprising: a housing (including 11, 30); a proximal portion 30, a distal portion 11, a seal material 20 made of rubber having non-compressible characteristics; a proximal guide tube 14, a distal guide tube (including the portion of element 16 and extending through element 36 and also a part of element 11); a ridge and groove 31, 32 (Figs. 1-5) are the means adjustably moving the proximal housing portion axially relative to the distal housing portion to increase the pressure of the incompressible seal on the instrument and to create a locking force tending to inhibit movement of the instrument relative to the valve; a Luer lock 13 coupled to the distal housing portion

Abramson discloses the seal material 20 but does not including the seal material is a gel; the proximal housing portion is not adjustably axially relative to the distal housing portion.

Weinstein discloses a surgical valve similar to the claimed of invention. Furthermore, Weinstein further comprising: a gel 30 made of silicone or petroleum jelly disposed in the gel cavity (Figs. 2-3). As noted that silicone gel is non-compressible pressure.

*Alternatively*, Brustad discloses a surgical valve comprising: a housing; a seal material 54a disposed in the gel cavity 35a; the seal material having non-compressible characteristic, see para [0033].

Johnson discloses a surgical valve comprising: a housing including a proximal housing portion 27; distal housing portion 22; the proximal housing portion is adjustably movable axially relative to the distal housing portion to increase the pressure of the seal/valve 10 on the instrument and to create a locking force tending to inhibit movement of the instrument relative to the valve.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Abramson with a gel material, as taught by Weinstein or Brustad, in order to increase the pressure on an instrument and enhance the sealing characteristic.

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It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Abramson with the proximal housing is adjustably movable axially relative to the distal housing, as taught by Johnson, in order to create a locking force for preventing movement of the instrument relative to the valve.

*Additionally, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e. for creating a pressure on an instrument extending through the valve to form a seal around the instrument; ...to increase the pressure of the incompressible gel on the instrument and to create a locking force tending to inhibit movement of the instrument relative to the valve, as functional limitations, do not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974).*

## **(10) Response to Argument**

### **A. Independent Claims 1 and 10**

#### **1. Applicant argues that Abramson teaches away from increasing pressure on a seal material to form a seal around an instrument.**

First, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., increasing pressure on a seal material to form a seal around an instrument) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claim 1 only requires that the gel having characteristics for creating (but not increasing) pressure on an instrument.

Second, Abramson clearly discloses that the domed construction is that the valve is capable of sealing extremely high pressures on the domed side. In short, the principle on the domed side serving to seal the slit, under closed conditions, even more tightly. Such a high pressure condition is encountered where the valve is sealed to maintain a pumped up pressure in some medical device as, for example, the cuff or an endotracheal tube, see col. 4, lines 49-59.

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Third, the combination of device Abramson in view of Weinstein or Brustad is used for enhancing the sealing around the medical instrument. As noted that, rubber material, as described in Abramson, is well known in the valve art for sealing characteristics. Besides that, when the male connector 40 of the instrument (syringe S) inserted through the valve slit 22 will be created a pressure on the syringe instrument will be created. Also, if the valve slit valve 22 is small and the diameter of male connector 40 is larger the diameter of slit valve, this causes an increasing pressure on the seal material to form a tight seal around the male connector or the medical instrument.

Abramson discloses a seal material is not a gel. However, Weinstein or Brustad suggests that a gel material 30 (Weinstein) or 54 (Brustad) for enhancing the sealing characteristic. Furthermore, Brustad discloses that the zero gel 58 formed solely by the gel material 54 ([0028]) or the gel material is a non-compressible [0033]) is same as the gel material with claimed invention as discussed on page 11, lines 8-9 and page 12, line 15 of the Specification. Therefore, the gel material of Weinstein or Brustad is able to create the pressure on the instrument extending through the valve to form a seal around the instrument.

One skill in the art would recognize that modifying the device of Abramson with the gel material, as taught by Weinstein or Brustad, for enhancing sealing instrument.

**2. Applicant argues that Abramson does not disclose or suggest a valve 20 that seals with an instrument inserted therethrough. (page 7 of Appeal Brief).**

In response, Abramson clearly shows in Fig. 3 that the instrument (syringe S) is not only inserted into the top part of the valve 20 but also able to insert into the valve 20, col. 5, lines 29-30. At this point, when the slit valve 22 is opened, the valve 20 still seals around the male connector 40 of syringe. Abramson clearly states that the tip of the male connector sealing engages the dome of the disc to bow the same outwardly accompanied by spreading the slit but short of the penetration thereof to permit flow of fluid through the opening with resilient reclosure of the slit as the connector is subsequently withdrawn, col. 6, lines 14-20 and col. 3, line 55-col. 4, line 8.

*Additionally, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e. for creating a pressure on an instrument extending through the*

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*valve to form a seal around the instrument; ...to increase the pressure of the incompressible gel on the instrument and to create a locking force tending to inhibit movement of the instrument relative to the valve, as functional limitations, do not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974).*

In this instance, the combination of device Abramson in view of Weinstein or Brustad and Jonson is able to performing the above function. Abramson clearly shows in Fig. 3 that the instrument (syringe S) is not only inserted into the top part of the valve 20 but also able to insert into the valve 20, col. 5, lines 29-30. As note that, one skill in the art would recognize that the device of Abramson can be provided any medical instrument such as catheter, trocar, syringe, guidewire... or even the different size of medical instrument can be inserted therethrough the valve 20 as intended use. For example: the diameter of medical instrument inserting into the slit valve; wherein the diameter of slit valve is smaller than the diameter of medical instrument will create the pressure on instrument extending through the valve to form a seal around the instrument.

The different between the seal valve of Abramson and the claimed invention is that the seal valve of Abramson made of soft rubber but is not in a gel. However, Weinstein or Brustad suggests that the gel is provided in the valve system. Therefore, one skill in the art would recognize that modifying the device of Abramson with the gel, as taught by Weinstein or Brustad, for enhancing sealing characteristics.

**3. Applicant argues that Abramson does not disclose a locking force tending to inhibit movement of an instrument. (Page 8 of Appeal Brief).**

In response, Abramson clearly discloses a ridge 31 and groove 32 to create a locking force tending to inhibit movement of the instrument, see Figs. 1, 3-5 and col. 3, lines 32-54.

The proximal housing portion 12 or 30 and distal portion 11 are pressed together with snapping in place of the detent while the claimed invention required adjustably movable axially. Meanwhile, Johnson discloses similar to the surgical valve comprise: the proximal housing portion 27 includes a thread section

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and engaged with the thread section of distal housing portion 22, see Fig. 5. One skill in the art would know that the thread sections are engaged to each other by adjustably movable axially direction.

Therefore, the device Abramson modified with the thread sections, as taught by Johnson, is provided in order to create a locking force for preventing movement of the instrument relative to the valve.

Applicant further argues that Abramson does not disclose or suggest inserting an instrument through the valve.

In response, similar to the response argument under section 2 above, Abramson clearly shows in Fig. 3 that the instrument (syringe S) is not only inserted into the top part of the valve 20 but also able to insert into the valve 20, col. 5, lines 29-30.

**4. Applicant argues that Abramson does not disclose or suggest adjustability between a first housing portion and a second housing portion. (Page 8 of Appeal Brief).**

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, Abramson provides the locking means 31 and 32 with snapping in place of the detent, see Fig. 1-5 and col. 3, lines 50-53. However, Johnson shows that the first housing portion 27 screwed or threaded to the second housing portion 22 or 24. As noted that, threading between the first and second housing portion is same as being adjustable between the two housing portions.

**5. Applicant argues that Abramson does not disclose or suggest a non-compressible rubber (Page 9 of Appeal Brief).**

In response, the claim 1 only requires the material having non-compressible characteristics. Meanwhile, Abramson discloses the valve formed of rubber and not limited to natural or synthetic rubber or rubber like plastics having similar durometer characteristics, col. 5, lines 43-47. As noted that,



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synthetic rubber such as silicone is also having non-compressible characteristics also. Beside that, it is well-known in the valve art that the material of valve having non-compressible (such as natural rubber or silicone rubber) as discussed in Weinstein et al. (element 30, col. 3, lines 6-7) or Johnson et al. (element 11, col. 2, lines 49-51), or Brustad clearly discloses that the gel 54 is a non-compressible, see para[0033].

Therefore, the device of Abramson in view of Weinstein or Brustad and Johnson discloses the claimed invention.

**6 & 7. Applicant argues that Weinstein does not disclose or suggest inhibiting movement of the instrument. There is no reasonable expectation of success in combining Abramson with Weinstein (Pages 9-10 of Appeal Brief).**

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, claim 1 or claim 10 requires that: the proximal housing portion (or the second housing portion) is adjustable movable axially relative to the distal housing portion (or first housing portion) to increase the pressure of the incompressible gel on the instrument and to create a locking force tending to inhibit movement of the instrument relative to the valve. The limitation above is covered in the device of Johnson.

Similarly to the rejection and the Response to the Argument under section 4 above, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, Abramson provides the locking means 31 and 32 with snapping in place of the detent, see Fig. 1-5 and col. 3, lines 50-53. However, Johnson shows that the first housing portion 27 screwed or threaded to the second housing portion 22 or 24. As noted that, threading between the first and second housing portion is same as being adjustable between the two housing portions.

The benefit of using gel of Weinstein into the device of Abramson is that including the benefits of providing high viscosity of the gel and sealing characteristics.

**8. Applicant argues that Johnson does not disclose creating a locking force tending to inhibit movement of an instrument (Page 10 of Appeal Brief).**

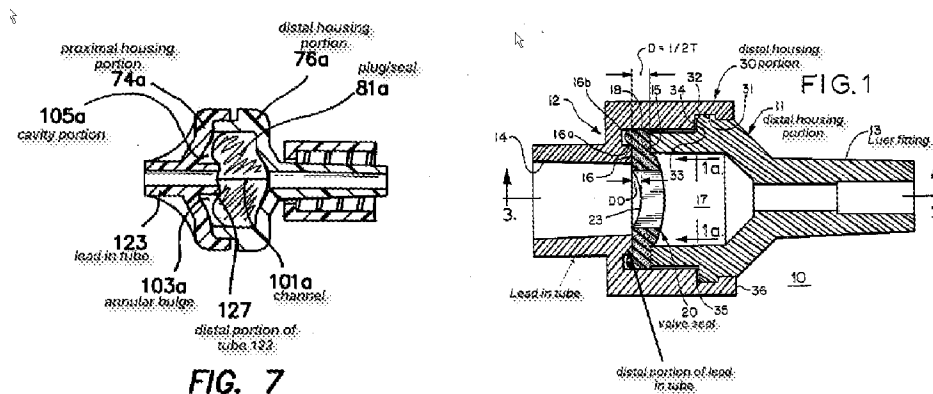
In response, as discussed in the Response to Argument parts 3-4 above, Abramson clearly suggest that locking means 31 and 32 (Figs. 1-5) is creating a locking force tending to inhibit movement of an instrument. Johnson also discloses similar to the surgical valve comprise: the proximal housing portion 27 includes a thread section and engaged with the thread section of distal housing portion 22, see Fig. 5. One skill in the art would know that the thread sections are engaged to each other by adjustably movable axially and the thread sections are of particular advantage in producing the locking force. Applicant also admitted on page 16, lines 4-5 of the Specification.

Therefore, the device Abramson modified with the thread sections, as taught by Johnson, in order to create a locking force for preventing movement of the instrument relative to the valve.

**9. Applicant argues that Examiner does not cite a disclosure or suggestion of limitation:**  
**the distal guide facilitating retrograde insertion of the surgical instrument into the surgical seal.**

In response, the device structure of Abramson is similar to the device structure of claimed invention. Therefore, it is capable of performing this function above.

As noted that, there is no different between the device of claimed invention and Abramson below:



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**10. Applicant argues that the combining the references are impermissible. (Page 11 of Appeal Brief).**

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

**B. Applicant believes that claims 2, 4-5 are dependent on claim 1 and are also allowable.**

Applicant's arguments have been fully considered but they are not persuasive. Therefore, the rejection of claims 2, 4-5 is thus maintained.

**C. Independent claim 6:**

**1&2. Applicant argues that Examiner does not identify any disclose or suggestion of either a node or an axial channel in any of the cited references.**

In response, Applicant recites the element 116 is a dome shaped or a node. Similarly, Abramson clearly states that the valve 20 is a domed construction, col. 4, lines 48-50 or Fig. 3. Under the compression The valve 20 also includes the channel at slit 22 to permit flow of fluid through the through-opening with resilient reclosure of the slit, col. 6, lines 14-20 and Figs. 1 and 3.

As noted, the dome shaped is located forward at distal housing portion, however, claim 6 only requires that the valve/seal material includes a node/dome shaped, therefore, the device of Abramson renders claimed subject matter in claim 6.

Beside that, the gel/seal of Weinstein or Johnson also includes the node/dome-shaped and the medical instrument passing through the axial channel of valve/seal.

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**3 & 4. Applicant argues that examiner identify any disclose the limitation of applying a force to the seal material sufficient to place the axial channel in a closed state. Abramson teaches against the subject matter of claim 6.**

In response, the limitation “applying a force to the seal material in the subassembly” in claim 6 as a method of performing in the structure device, this is considered as a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974). In this case, the device of Abramson is capable of performing this function such as when the male connector 40 of syringe S is touching the surface of valve 20, but not pressing hard enough, when the valve 20 still is in the closed condition. Alternatively, Weinstein shows in Figs. 2 that under applying the force of the proximal housing 16 and distal housing portion 14 are engaged with each other, the seal material 24/30 is still in a closed state.

**5. Applicant argues that the Examiner’s reasons for combining the reference are irrelevant to claim 6.**

Applicant states that the Examiner’s reasons for combining the references invoke the interaction between a valve and an instrument, see page 12 of Appeal Brief. However, Applicant does not specifically point out the improper or irrelevant reasons. The Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the combination of Abramson in view of Weinstein or Brustad and Johnson clearly show all claimed subject matter as discussed above.

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**D. Applicant believes that claims 7-9 are dependent on claim 6 and are also allowable.**

Applicant's arguments have been fully considered but they are not persuasive. Therefore, the rejection of claims 7-9 is thus maintained.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Quynh-Nhu H. Vu/

Examiner, Art Unit 3763

Conferees:

Nick Lucchesi

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763

Tatyana Zalukaeva

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761